Applicants have amended the Brief Description of the Drawings and respectfully submit that the objection no longer applies to the specification as amended.

In accordance with 37 C.F.R. § 1.121, a marked up copy of the presently amended table in the specification and the description of Figure 3A, 3B, and 3C is appended hereto. Deletions to the originally filed text are noted by bracketing; additions are noted by underlining.

The Examiner has required restriction under 35 U.S.C. § 121 of the application into one of three allegedly distinct inventions. Applicants hereby elect to prosecute the claims encompassed by Group I, claims 1-33, drawn to a method of altering a B cell mediated pathology by administering a chimeric protein, classified in Class 514, subclass 885, and Class 424, subclass 133.1.

The Examiner has alleged that the claimed invention of Groups I and II contains the following patentably distinct species of the claimed invention wherein the chimeric protein comprises:

A) a portion of a VH linked to a portion of a constant region without a portion of a VL linked to a portion of a constant region,

B) a portion of a VL linked to a portion of a constant region without a portion of a VH linked to a portion of a constant region, or

C) both a portion of a VH linked to a portion of a constant region and a portion of a VL linked to a portion of a constant region.

The Examiner alleges that chimeric proteins comprising only a VH, only a VL, or a VH+VL each differ in structure and physiological properties, and that therefore each form of chimeric proteins represent patentably distinct subject matter.

The Examiner therefore requires election under 35 U.S.C. 121 to a single species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicants respectfully traverse the Examiner's requirement for election of a species to be examined. A method of treatment wherein the variable region from a patient's idiotype (Id) protein is linked to a portion of a constant region does not depend on differences in the structure

and physiological properties of the resultant chimeric proteins other than the region for the Id protein derived from the patient.

Nevertheless, to facilitate the prosecution the claims of Group I of instant application, Applicants elect 'C' as set forth above, *i.e.*, both a portion of a VH linked to a portion of a constant region and a portion of a VL linked to a portion of a constant region.

The Examiner has alleged that the claimed invention of Groups I and II contains the following patentably distinct species of the claimed invention wherein the portion of the immunoglobulin VH constant region is:

A) human IgG1,
B) human IgG2,
C) human IgG3,
D) human IgG4,
E) human IgA1,
F) human IgA2,
G) human IgM,
H) human IgD, or
I) human IgE.

The Examiner alleges that each VH constant region differs in structure and physiological properties, and that therefore each represents patentably distinct subject matter.

The Examiner therefore requires election under 35 U.S.C. 121 to a single species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicants respectfully traverse the Examiner's requirement for election of a species to be examined. A method of treatment wherein the variable region from a patient's Id protein is linked to a portion of a constant region does not depend on differences in the structure and physiological properties of the resultant chimeric proteins. All of the listed constant regions will serve to provide a scaffold for carrying the portion of the Id protein cloned from the patient and thus provide a means for altering the response to a B cell pathology.

Nevertheless, to facilitate the prosecution the claims of Group I of instant application, Applicants elect 'A' as set forth above, *i.e.*, a VH constant region of human IgG1.

The Examiner has alleged that the claimed invention of Groups I and II contains the following patentably distinct species of the claimed invention wherein the portion of the immunoglobulin VL constant region is:
A) a human kappa constant region, or
B) a human lambda constant region.

The Examiner alleges that each VL constant region differs in structure and physiological properties, and that therefore each represents patentably distinct subject matter.

The Examiner therefore requires election under 35 U.S.C. 121 to a single species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicants respectfully traverse the Examiner's requirement for election of a species to be examined. A method of treatment wherein the variable region from a patient's Id protein is linked to a portion of a constant region does not depend on differences in the structure and physiological properties of the resultant chimeric proteins. Both of the listed constant regions will serve to provide and are used to provide a scaffold for carrying the portion of the idiotype (Id) protein cloned from the patient and thus provide a means for altering the response to a B cell pathology. Further, we note that in the method of the instant invention, the choice between kappa and lambda light chains is made based on what is expressed in the patient's B cell clone associated with the B cell pathology to be treated.

Nevertheless, to facilitate the prosecution the claims of Group I of instant application, Applicants elect 'A' as set forth above, *i.e.*, a VL constant region of the human kappa chain.

The Examiner has alleged that the claimed invention of Groups I and II contains the following patentably distinct species of the claimed invention wherein the composition:
A) does not further comprise a carrier protein, a cytokine, or a chemokine;
B) further comprises a carrier protein, but not a cytokine or a chemokine;
C) further comprises a cytokine, but not a carrier protein or a chemokine;

D) further comprises a chemokine, but not a carrier protein or a cytokine;
E) further comprises both a carrier protein and a cytokine, but not a chemokine;
F) further comprises both a carrier protein and a chemokine, but not a cytokine;
G) further comprises both a cytokine and a chemokine, but not a carrier protein; or
H) further comprises a cytokine, a chemokine, and a carrier protein.

The Examiner alleges that each composition differs in its individual components and has different physiological properties, and that therefore each represents patentably distinct subject matter.

The Examiner therefore requires election under 35 U.S.C. 121 to a single species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicants respectfully traverse the Examiner's requirement for election of a species to be examined. The physiological properties of the means for presenting the chimeric protein to the immune system of the patient together with a means to stimulate the immune response of the patient do not create patentably distinct inventions where the present invention is a method of treatment wherein the variable region from a patient's Id protein is linked to a portion of a constant region.

Nevertheless, to facilitate the prosecution the claims of Group I of instant application, Applicants elect 'E' as set forth above, *i.e.*, wherein the composition further comprises a carrier protein and a cytokine.

The Examiner has alleged that the claimed invention of Groups I and II contains the following patentably distinct species of the claimed invention wherein the chimeric protein can be isolated with:
A) protein A,
B) protein G, or
C) protein L.

The Examiner alleges that each protein differs in their structure and with respect to which immunoglobulin constant regions each protein binds, and that therefore each represents patentably distinct subject matter.

The Examiner therefore requires election under 35 U.S.C. 121 to a single species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicants respectfully traverse the Examiner's requirement for election of a species to be examined. A method of treatment wherein the variable region from a patient's Id protein is linked to a portion of a constant region does not depend on the protein used to purify the chimeric protein carrying the portion of the Id protein cloned from the patient to provide a means for altering the response to a B cell pathology.

Nevertheless, to facilitate the prosecution the claims of Group I of instant application, Applicants elect 'A' as set forth above, *i.e.*, protein A.

The Examiner has alleged that the claimed invention of Groups I and II contains patentably distinct species of the claimed invention wherein the B cell mediated pathology is one of the B cell mediated pathologies set forth in claims 48, 49, or 51, *i.e.*, non-Hodgkins lymphoma; refractory low grade or follicular B cell lymphoma; or is an autoimmune disease selected from the group consisting of multiple sclerosis, systemic lupus erythematosus, anti-Hu associated paraneoplastic neurological syndrome, autoimmune hepatitis, Type I diabetes, autoimmune thyroiditis, and scleroderma.

The Examiner alleges that each pathology differs with respect to its pathophysiology and patient population, and that therefore each represents patentably distinct subject matter.

The Examiner therefore requires election under 35 U.S.C. 121 to a single species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicants respectfully traverse the Examiner's requirement for election of a species to be examined. A method of treatment wherein the variable region from a patient's Id protein is

linked to a portion of a constant region does not depend on the protein used to purify the chimeric protein carrying the portion of the Id protein cloned from the patient to provide a means for altering the response to a B cell pathology to all of the above B cell mediated pathologies. Patients suffering from any of the above conditions could be treated by the methods of the instant invention with only minor adjustments within the ability of one skilled in the art.

Nevertheless, to facilitate the prosecution the claims of Group I of instant application, Applicants elect non-Hodgkins lymphoma.

The Examiner has alleged that the claimed invention of Group III contains the following patentably distinct species of the claimed invention wherein the vector comprises:
A) SEQ ID NO:6,
B) SEQ ID NO:7,
C) SEQ ID NO:89,
D) SEQ ID NO:90, or
E) SEQ ID NO:91.

The Examiner alleges that each vector differs in its structure/sequence, and that therefore each represents patentably distinct subject matter.

The Examiner therefore requires election under 35 U.S.C. 121 to a single species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicants respectfully submit that the species election requirement is moot as the claims of invention III are no longer pending in this application. Applicants again reserve the right to pursue this above canceled subject matter in this or any other appropriate patent application.

CONCLUSION

It is believed that all claims are now in condition for allowance. Notification to that effect is respectfully requested. If it is believed that prosecution may be furthered thereby, the Examiner is invited to contact Applicant's undersigned representative to discuss the same. If, however, any fee should become due or credit become payable during the pendency of this

application, the Patent Office is authorized to charge or credit the same to Deposit Account 03-3975, referencing Docket No. 027579.0302598.

Respectfully Submitted,

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